



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,057	02/05/2001	Colin Brown	9052-67	1282

20792 7590 04/21/2006

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
----------	--------------

1623

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,057

Applicant(s)

BROWN, COLIN

Examiner

Everett White

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23 and 26-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23 and 26-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>Jan. 17, 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on January 17, 2006 has been entered.
2. The Information Disclosure Statement (IDS) filed January 17, 2006 has been received, entered and carefully considered.
3. Claims 1-22, 24, 25 and 36-44 were previously canceled.
4. Claims 23 and 26-35 are pending in the case.
5. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

6. Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 30 and 31, line 2 of each claim, the phrase "the peritoneal cavity" lacks clear antecedent basis by being dependent from Claim 23, which renders the claims indefinite.

Claim Rejections - 35 USC § 103

7. Claims 23 and 26-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobbie ("Separation of Peritoneal Surfaces Through the Maintenance of an Artificial Ascites as a Preventative of Peritoneal Adhesions" Abstract, from The 4th

Art Unit: 1623

Peritoneum and Peritoneal Access Meeting, September 16-19, 1997) in view of Milner (US Patent No. 4,886,789, already of record).

Applicant claims a method of reducing the incidence of adhesions in a body cavity, comprising introducing into the body cavity a composition comprising an aqueous formulation further comprising a polysaccharide dextrin in an amount effective to reduce the incidence of said adhesions, wherein the dextrin is unsubstituted and the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12 and acts as an osmotic agent to maintain a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other, and wherein the aqueous formulation is a solution in the body cavity and further remains in the body cavity for at least 2 days. Additional limitation in the dependent claims include the method wherein said composition is applied to the appropriate body cavity after a surgical operation has been carried out; the method wherein the composition is allowed to remain in the body cavity for a minimum of 2 to 3 days; the method wherein the composition is allowed to remain in the body cavity over the period during which fibrin exudation is at a maximum; the method wherein the Composition remains in the body cavity for a period of up to 7 to 8 days in order to allow restoration of non-stick surfaces; the method wherein the composition is applied to the peritoneal cavity in a volume in the range of 500-2000 ml; the method wherein the dextrin is applied to the appropriate body cavity in differing concentrations over a concentration range of 2.5- 18 % weight to volume of the composition; the method wherein the concentration range of the dextrin is selectively altered over a period of time.

The abstract of the Dobbie reference discloses development of Icodextrin (glucose polymer) as a non-glycating, long-dwell, peritoneal solution of physiological osmolarity for use in peritoneal dialysis as a dialysate, a carrier solution for continuous ambulatory chemotherapy, and for use post-operatively in patients with a high risk of abdominal adhesions. This statement embraces the general description of the instantly claimed method of reducing the incidence of adhesions in a body cavity since the terms

Art Unit: 1623

Icodextrin, peritoneal, non-glycating, and long-dwell all suggest the dextrin, body cavity, unsubstituted dextrin and the period of time disclosed in the instant claims.

The instantly claimed method of reducing the incidence of adhesion in a body cavity differs from the separation of peritoneal surfaces described in Dobbie reference by claiming that the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12.

However, the Milner patent shows that dextrin having 15% polymers with a degree of polymerization greater than 12 is well known in the art. The Milner patent discloses a peritoneal dialysis composition containing an osmotic agent comprising a glucose polymer mixture, said mixture including at least 15% by weight of glucose polymers having a DP greater than 12 (see abstract). See column 6, line 39 and 43, wherein preparation of the glucose polymer mixture is described and wherein the term dextrinised starch is mention, which suggest that the glucose polymer mixture of the Milner patent is dextrin. Also see column 9, line 9, wherein the Milner patent describes a typical peritoneal dialysis solution as comprising 2 to 15% w/v of glucose polymer, which falls within the amount of concentrated dextrin that may be applied to a body cavity disclosed in instant Claims 32-34. See column 11, lines 22-24 wherein the Milner patent describes an infusion of peritoneal dialysis solutions is 2 liters in volume, wherein a total amount of infusion may be 6 liters per day, which embraces the subject matter of instant Claims 30 and 31.

One of ordinary skill in this are would be motivated to combine the teachings of the Dobbie reference with the Milner patent since both references discloses the application of a dextrin solution to the peritoneal cavity.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the dextrin used to reduce the incidence of adhesion in a body cavity of the Dobbie reference with dextrin having 15% polymers with a degree of polymerization greater than 12 in view of the recognition in the art, as evidenced by Milner patent, that dextrin having 15% polymers with a degree of polymerization greater than 12 are more effective as osmotic agents than would be indicated by calculation based on the standard assumption that each molecule of such a

Art Unit: 1623

polymer would be osmotically the equivalent of one molecule of dextrose or any other compound.

Summary

8. All the pending claims (Claims 23 and 26-35) are rejected.

Examiner's Telephone Number, Fax Number, and Other Information


9. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang, can be reached on (571) 272-0627. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


E. White


Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600